This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0049

CUSTOMER NO. 1503

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

STILLMEADOW, INC.
12852 PARK ONE DRIVE
SUGAR LAND, TX 77478
(281) 240-8828

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS*(sites)*

See Attached Listing

COPY FOR YOUR INFORMATION

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	73	344		2	346 419
5. Cats	11	108 98		10	119 108
6. Guinea Pigs		1904		58	1962
7. Hamsters					
8. Rabbits		1056		100	1156
9. Non-Human Primates					
10. Sheep					
11. Pigs		37			37
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SI

(b)(6), (b)(7)c

DATE SIGNED
7 Nov 07

AP

EADQUARTERS

Column "E" Explanation

- The introduction of additional chemicals (pain relieving drugs) with potent physiological action(s) would likely alter the response of the animals to the substance the study is designed to test, therefore invalidating the results. The purpose of safety studies (with protocols usually approved either by the FDA or EPA) is to accurately determine whether or not administration of the test material will have any adverse affect on the subjects. If adverse results are masked by use of pain relieving drugs, dangerous products could very well be released to the market, causing unpleasant or even dangerous symptoms in household pets that should have been detected in test trials

- **Dogs** – In two safety studies, 2 animals experienced adverse reactions to the administration of a test material. One was found dead, and one was euthanized. The remaining animals on the study were carefully monitored, but did not exhibit any pain or distress.

- **Cats** - The amount of stress exhibited by the flea host cats is minimal at worst. The collection of flea eggs is essential to the conduct of our studies to determine the efficacy of flea prevention/elimination products. The effects of the reaction of the flea eggs to analgesics or anesthetics are not known, but the risk cannot be taken that any drug might adversely affect the health of the flea eggs. Reliable test results would be in jeopardy if the initial flea and flea egg health cannot be assured.

  We are aware that an artificial host system exists, but find that it is not well suited to our applications. The artificial system cannot simulate a home environment, which is one of the aspects of our studies that our clients find particularly appealing.. Fleas from an artificial system do not adapt consistently to the host animals.

- **Guinea Pigs** - Guinea pigs used in dermal sensitization studies according to the Buehler method are restrained for six hours, usually four times at weekly intervals. The restrained animals rarely seem anxious to escape from the restrainers and they are adjacent to, and can see, other restrained animals in their test group. Again, drugs of any kind can potentially interfere with the response of the animals to the test substance, and guidelines do not make provision for use of tranquilizing, analgesic or anesthetic drugs in these studies. Guinea pigs used in Magnusson Kligman maximization studies are not restrained. However, most of the sensitization studies are conducted according to the Buehler method, which is generally preferred over the Magnusson Kligman method. Irritancy is a relatively minor issue in the sensitization tests. A range finding is conducted to identify a non-irritating dose – different concentrations of the test substance are tested in a few animals. In the main test the test substance usually does not produce significant irritation.

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- **Rabbits** - Many of the animal studies in this facility are conducted to define the local and/or systemic effects of exposure to a product consisting of one or more chemical substances. Typically, product labels will be based on this information with the ultimate goal of protecting people who use the products from hazards that studies have shown to exist. In order for these studies to be valid scientifically, exposure to additional chemicals of any kind should be avoided because of potential interference with the test subject's response to the test chemical(s). For this reason, the US and international guidelines that must be followed for these tests do not include provision for the use of drugs such as anesthetics, analgesics, or tranquilizers, with one exception (see below). Primary eye irritation and primary dermal irritation studies, as well as many of the acute dermal toxicity studies, employ rabbits as the test subject. In this laboratory in 2005, approximately 52% of the rabbits used were in dermal toxicity tests, 26% in eye irritation tests and 22% in dermal irritation tests. For the scientific and regulatory reasons outlined above, anesthetics and analgesics are not used except for some eye irritation studies. The guidelines do provide for use of a topical ophthalmic anesthetic in eye irritation studies, if there is reason to believe, on the basis of high or low pH, or knowledge of specific chemical properties of the test substance, that a severe effect on the eye might be anticipated. Actually, if a severe, corrosive effect is deemed certain, the guidelines indicate that the testing is not required at all. Also provided in both eye and dermal irritation study guidelines is provision for testing a single animal with the option to proceed to dose additional animals if the effect was not severe, or to stop after dosing one animal if there were severe effects. Similarly there are provisions for timing the primary dermal irritation exposure, i.e., using first a three-minute exposure, then if no severe effects occur, a one-hour exposure, and only then if no severe effects have occurred, the typical four-hour exposure period. Also, this laboratory has developed a guidance document covering euthanasia for humane reasons in case of severe systemic or local effects. This would be more likely to come into play in dermal toxicity studies. In actual experience with product testing, severe effects are uncommon.

  USEPA Health Effects Test Guideline, Office pf Prevention, Pesticides and Toxic Substances, OPPTS 870-1200, Acute Dermal Toxicity, OPPTS 870.2400, Acute Eye Irritation, OPPTS 870-2500, Acute Dermal Irritation, OPPTS 870-2600, Guinea Pig Sensitization

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